DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 14, 2014

Stryker Orthopaedics
Ms. Denise Daugert
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K142462
Trade/Device Name: Restoration Anatomic Shell
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: August 29, 2014
Received: September 2, 2014

Dear Ms. Daugert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142462

Device Name: Restoration Anatomic Shell

Indications for Use:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

The Restoration® Anatomic Shell is indicated for cementless use only.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Sponsor	Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430
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Date Prepared:	August 29, 2014
Proprietary Name:	Restoration Anatomic Shell
Common Name:	Total Hip Joint Replacement
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. (888.3358)
Product Codes:	LPH

Legally Marketed Device to Which Substantial Equivalence is claimed:

- Trident Porous Titanium Acetabular Shell (K010170)
- S-ROM Oblong Cup (K905258)

Device Description:

The Restoration Anatomic Shell is intended for cementless fixation into a prepared acetabulum for either primary or revision Total Hip Arthroplasty. The basic design of the Restoration Anatomic Shell is similar to two other commercially available total hip systems, which are Stryker Orthopaedics' Trident Porous Titanium Acetabular Shell, and DePuy's S-ROM Oblong

Cup. The Restoration Anatomic Shell will be available in 14 sizes, 54mm - 80mm diameter in 2mm increments. There will be a left and right shell configuration for each size. The subject device is designed to accept the existing Modular Dual Mobility (MDM) liners. The locking mechanism is identical to the locking mechanism of the predicate Trident Porous Titanium Acetabular Shell. The implant will be made of Ti-6Al-4V ELI alloy (ASTM F136) and will have a porous Commercially Pure (CP)-Ti (ASTM F1580) coating allowing for biological fixation. The inner locking mechanism is positioned eccentrically relative to the outer surface of the shell, thus creating a build-up of solid material intended to be positioned in the superior region of the acetabulum. The area outside the locking mechanism will have a recessed or beveled surface to reduce the amount of implant that is exposed outside of the native acetabulum. The shell will have multiple screw hole options located in the superior and inferior regions of the shell as well as peripheral screw holes located outside the locking mechanism. The Restoration Anatomic Shell is compatible with the optional currently marketed Stryker Orthopaedics Acetabular Dome Hole Plug made from CP Titanium (ASTM F-67).

Intended Use: The Restoration Anatomic Shell is intended for use in total hip arthroplasty and is intended for either primary or revision Total Hip Arthroplasty.

Indications for Use:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

The Restoration Anatomic Shell is indicated for cementless use only.

Summary of Technological Characteristics: Device Comparisons show that the Restoration Anatomic Shell is substantially equivalent to its predicates in terms of intended use, indications, design, materials, performance characteristics and operational principles.

Non-Clinical Testing: The following non-clinical laboratory testing was performed to determine substantial equivalence:

1) Push-out Test of a Modular Dual Mobility Liner in a Deformed Shell
2) Acetabular Wedge Augment Device Fatigue Model
3) Mechanical Properties of the Tritanium Foam Coating
4) Material Microstructure, Composition, and Trace Elemental Analysis of the Substrate and Surface of the Tritanium Acetabular Shells
5) Structural Characteristics of the Tritanium Foam Coating

Clinical Testing: Clinical testing was not required as a basis for substantial equivalence.

Conclusion: The Restoration Anatomic Shell is substantially equivalent to the predicate devices identified in this premarket notification.